5. 510(K) SUMMARY

APR 0 8 2014

DATE SUMMARY PREPARED: 23 January 2013

OWNER:
Baxter Healthcare Corporation
One Baxter Way
Westlake Village, CA 91362

CONTACT PERSON:
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Associate Director, Global Regulatory Affairs
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DEVICE NAME:

Trade Name: ALTAPORE

Common Name: Bone Void Filler

Classification: Resorbable calcium salt bone void filler devices have been classified by the Orthopedics Device Panel as Class II Special Controls per 21CFR888.3045

Class: Class II

Product Code: MQV

PREDICATE DEVICES

K071206	Actifuse® ABX E-Z-fil Putty Bone Graft Substitute
K081979	Actifuse® Bone Graft Substitute Actifuse® ABX E-Z-fil Putty Bone Graft Substitute Actifuse® Shape Bone Graft Substitute Actifuse® Flow Bone Graft Substitute
K082575	Actifuse® Bone Graft Substitute Actifuse® Microgranules Bone Graft Substitute Actifuse® E-Z Prep Actifuse® ABX E-Z-fil Putty Bone Graft Substitute Actifuse® MIS Actifuse® Shape Bone Graft Substitute

DEVICE DESCRIPTION:

ALTAPORE is a bioactive and osteoconductive silicate-substituted calcium phosphate bone void filler. The interconnected and open porous structure of the silicate-substituted calcium phosphate phase of ALTAPORE is similar to human cancellous bone and is intended to support bone growth with macro- and micro- porosity. ALTAPORE is composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si). ALTAPORE is supplied in a sterile applicator and contains ALTAPORE microgranules, sized 1–2 mm, 80-85% total porosity, suspended in an absorbable aqueous gel carrier. ALTAPORE does not set in-situ following implantation. ALTAPORE is available in 1.5ml, 2.5ml, 5ml, 10ml, and 20ml configurations.

ALTAPORE is designed for use as a standalone bone graft substitute or as an autograft extender. While not necessary, the product can be mixed with Bone Marrow Aspirate (BMA) or autologous bone at the discretion of the surgeon.

ALTAPORE is bioactive based on *in vitro* studies that show it forms a surface apatite-layer when submerged in simulated body fluid that contains the same ion concentrations as human blood plasma. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect.

ALTAPORE is osteoconductive based on *in vivo* animal studies that show it achieves bony healing in a critical defect model as confirmed with radiographic, histolopatholgical, histomorphometric, and mechanical analyses. ALTAPORE undergoes cell-mediated remodeling and is replaced by natural bone.

STATEMENT OF INTENDED USE:

ALTAPORE is an implant intended to fill bony voids or gaps of the skeletal system i.e., extremities and pelvis. ALTAPORE can be used in combination with autograft as a bone graft extender in the extremities and pelvis. ALTAPORE can be used in combination with autogenous bone marrow aspirate in the extremities and pelvis. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ALTAPORE resorbs and is replaced with bone during the healing process.

TECHNOLOGICAL CHARACTERISTICS:

ELEMENT OF COMPARISON	ALTAPORE	PREDICATE (ABX)
Composition	Silicate-substituted calcium phosphate composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).	Silicate-substituted calcium phosphate composed solely of elements that exist naturally in normal bone (Ca, P, O, H, Si).
Physical Structure	Granules with a porosity similar to cancellous bone	Granules with a porosity similar to cancellous bone
Nominal (Total) Porosity	82.5 ± 2.5%	80.0 ± 2.5%
Strut Porosity	Microporous	Microporous
Sterility	Terminal irradiation	Terminal irradiation

ASSESSMENT OF NONCLINICAL DATA:

Testing has shown ALTAPORE to meet the requirements of relevant standards for Calcium Salt Bone Void Fillers. Testing has confirmed ALTAPORE to be safe and effective in providing a scaffold for rapid bone repair via bony infiltration of the porous scaffold. Non-clinical testing included benchtop material characterization, dissolution, and mechanical; as well as *in-vitro* bioactivity . Biocompatibility of the device has been established in accordance with ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and Testing*. Critical size defect implantation *in-vivo* animal studies have demonstrated that ALTAPORE is efficacious as a standalone bone graft substitute, mixed with Bone Marrow Aspirate (BMA), or mixed with autologous bone.

CONCLUSIONS:

The conclusions drawn from the non-clinical tests demonstrate that ALTAPORE is as safe, as effective, and performs as well or better than the predicate devices as a bioactive and osteoconductive bone void filler for osseous defects and is therefore substantially equivalent to the predicate devices. ALTAPORE is efficacious as a standalone bone graft substitute, mixed with Bone Marrow Aspirate (BMA), or mixed with autologous bone. The side-by-side comparative benchtop, *in-vitro* and *in-vivo* performance data provided showed no evidence of local or systemic adverse effects related to the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2014

Baxter Healthcare Corporation
Mr. Jerzy Wojcik
Associate Director, Global Regulatory Affairs
One Baxter Way
Westlake Village, California 91362

Re: K130531
Trade/Device Name: ALTAPORE
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: March 13, 2014
Received: March 14, 2014

Dear Mr. Wojcik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130531

Device Name: ALTAPORE

Indication(s) for Use:

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Prescription Use: ☑	AND/OR	Over-the-Counter Use: ☐
21 CFR 801 Subpart D		21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130531